DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

111994 N

WARNING LETTER
SJN-98-16

August 12, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Julia Vélez Sanchez
Hospital Administrator
Hospital Dr. Susoni
Calle Palma # 55
Arecibo, PR 00612

Dear Ms. Sanchez:

During an inspection of your unlicensed hospital blood bank from July 15 to July 21, 1998, our investigator documented deviations from the Current Good Manufacturing Practices (GMP's) for Blood and Components (Title 21, Code of Federal Regulations, part 606).

These deviations cause the Blood and Blood products manufactured and tested by your firm to be adulterated within the meaning of section 501 (a) (2) (b) of the Food Drug and Cosmetic Act (the Act).

The specific deviations reported are the following:

1. Failure to have records of performance of a serological test for syphilis for eight (8) individual units of blood and failure to record results of a serological test for syphilis for all units processed on four (4) separate days. [21 CFR 606.160 (b) (2) (I)]. All units involved in these instances were recorded in the log book as non-reactive for syphilis and made available for distribution.

2. Donor interview technique observed during the inspection found incorrect explanation of the symptoms of Creutzfeldt-Jacob Disease and Chagas disease. [21 CFR 606.20 (b)].

3. Failure to quarantine and destroy a unit of blood, which was significantly below [redacted] the weight range of 425-520 grams, recommended by the manufacturer of the blood collection system. The unit was placed in the refrigerator and labeled as available for transfusion. [21 CFR 606.121 (b) (6)] .

The above identified deviations are not intended to be an all-inclusive list if deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the address on the letterhead above to the attention of Mary L. Mason, Compliance Officer.

Sincerely,

Samuel Jones
District Director

Cc: Dr. José A. Garcia Llorens
Board of Directors President
Hospital Dr. Susoni, Inc.
Calle Palma # 55
Arecibo, PR 00612